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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,355	02/04/2005	Ann-Margret Lindqvist	056291-5173	5755

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EXAMINER	
KUDLA, JOSEPH S	

ART UNIT	PAPER NUMBER
1609	

MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,355	LINDQVIST, ANN-MARGRET	
	Examiner	Art Unit	
	Joseph S. Kudla	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 8, 13, 14 and 18-20, drawn to a method of treating hypercholesterolemia and/or other forms of dyslipidaemia wherein said hypercholesterolemia and dyslipidaemias are characterized by defects in lipoproteins or their receptors, in a warm-blooded animal, such as man, in need of such treatment which comprises administering to said animal an effective amount of an IBAT inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

Group II, claim(s) 2, 9, 13, 14 and 15-20, drawn to a method of treating hypercholesterolemia and/or other forms of dyslipidaemia wherein said hypercholesterolemia and dyslipidaemias are characterized by defects in lipoproteins or their receptors, in a warm-blooded animal, such as man, in need of such treatment

which comprises administering to said animal an effective amount of an IBAT inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof in combination with an effective amount of an HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

Group III, claim(s) 3, 13, 14 and 18-20, drawn to a pharmaceutical composition which comprises an IBAT inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, in association with a pharmaceutically acceptable diluent or carrier for use in the treatment of hypercholesterolemia and/or other forms of dyslipidaemia wherein said hypercholesterolemia and dyslipidaemias are characterized by defects in lipoproteins or their receptors.

Group IV, claim(s) 4, 5, 11, 13, 14 and 15-20, drawn to a pharmaceutical composition which comprises an IBAT inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, in association with a pharmaceutically acceptable diluent or carrier, in combination with a pharmaceutical composition which comprises an HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate Of such a salt or a prodrug thereof, in association with a pharmaceutically acceptable diluent or carrier for use in the treatment of hypercholesterolemia and/or other forms of dyslipidaemia wherein said

hypercholesterolemia and dyslipidaemias are characterized by defects in lipoproteins or their receptors.

Group V, claim(s) 6, 13, 14 and 18-20, drawn to the manufacture of a medicament for use of an IBAT inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof in the treatment of hypercholesterolemia and/or other forms of dyslipidaemia wherein said hypercholesterolemia and dyslipidaemias arc characterized by defects in lipoproteins or their receptors, in a warm-blooded animal, such as man.

Group VI, claim(s) 7, 13, 14 and 15-20, drawn to the manufacture of a medicament for use of an IBAT inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, in combination with an HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, in the treatment of hypercholesterolemia and/or other forms of dyslipidaemia wherein said hypercholesterolemia and dyslipidaemias are characterized by defects in lipoproteins or their receptors, in a warm-blooded animal, such as man.

Group VII, claim(s) 10, 13, 14, and 15-20, drawn to a method of testing whether an IBAT inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof has any one of the following effects of lowering total cholesterol,

lowering LP-remnants optionally in combination with an HMG CoA reductase inhibitor, lowering LDL optionally in combination with an HMG CoA reductase inhibitor, raising HDL optionally in combination with an HMG CoA reductase inhibitor or exhibiting a synergistic effect in combination with an HMG CoA reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof on the lowering of the ratio of (LP-remnants + LDL-cholesterol)/(HDL-cholesterol); wherein the method of testing comprises administering the IBAT inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, to a transgenic LDL receptor and/or ApoE deficient non-human mammal optionally in combination with an HMG CoA reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof; and determining whether there has been an effect on the non human mammal.

Group VIII, claim(s) 12, 13, 14 and 15-20, drawn to a composition comprising an IBAT inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, and an HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, for use in lowering abnormal cholesterol and triglyceride levels and the composition of the different lipoproteins concerning cholesterol, triglycerides, and apolipoproteins in a warm-blooded animal, such as man, with hypercholesterolemia and/or other forms of dyslipidaemia wherein said hypercholesterolemia and dyslipidaemias are characterized by defects in lipoproteins or their receptors.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no special technical feature in the instant claim set.

The technical feature that applicant states in Groups I-VIII is an IBAT inhibitor to treat hypercholesterolemia. It has been shown in prior art cited by applicant (Higaki et al, Arteriosclerosis, Thrombosis, and Vascular Biology, 18(8), Aug. 1998, pp. 1304-1311) that IBAT inhibitors are effective to treat hypercholesterolemia (last sentence of Abstract). Claims 1-20 share a common technical feature, therefore; there is no special technical feature and thus the claims lack unity.

Applicant is required to elect a group to be examined on the merits.

3. The compounds of claims 13 and 14 encompass many different and distinct compositions. The compositions vary distinctly in their structures and functions. Thus, an individual search is required of each individual composition. Therefore, Applicant is required to elect a specific compound, to which the elected invention will be examined on the merits as drawn to (in the event that the elected compound cannot be found, the elected structure will be opened to a reasonable core.); as well as identifying those claims to which the elected compound is drawn. This requirement is *not* to be taken as an election of species, but rather as an election of a single invention, since each composition is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is required, in reply to this action, to elect a single compound to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected compound, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a compound(s) or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Election of Species

Type of HMG Co-A Reductase Inhibitor

4. Claims 15-17 are generic due to a plurality of the following disclosed patentably distinct antibiotic species represented in claims 15-17.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Type of Disease State

5. Claims 18-20 are generic due to a plurality of the following disclosed patentably distinct antibiotic species represented in claims 18-20.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Kudla whose telephone number is (571) 270-3288. The examiner can normally be reached on 9am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JK

MICHAEL MELLER
PRIMARY EXAMINER